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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/561,654	04/11/2006	Cornelia Hertel	21733	7862
151 7590 04/20/2007 HOFFMANN-LA ROCHE INC. PATENT LAW DEPARTMENT 340 KINGSLAND STREET NUTLEY, NJ 07110			EXAMINER PERREIRA, MELISSA JEAN	
			ART UNIT	PAPER NUMBER
			1618	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/20/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Application No.

10/561,654

Applicant(s)

HERTEL ET AL.

Examiner

Melissa Perreira

Art Unit	
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1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1:704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 March 2007.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,8 and 9 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,8 and 9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 3/16/07.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

Art Unit: 1618

DETAILED ACTION

Claims 1-3,8 and 9 are pending in the application. Claims 11 and 12 were cancelled in the amendment filed 3/16/07. Any objections and/or rejections from previous office actions that have not been reiterated in this office action are obviated.

Response to Arguments

1. Applicant's arguments, see remarks, filed 3/16/07, with respect to **Claim Rejections - 35 USC § 102** Dean et al. (WO97/22367) have been fully considered and are persuasive. The rejection of claims 1-3,8 and 9 has been withdrawn.
2. Applicant's arguments filed 3/16/07 have been fully considered but they are not persuasive.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-3,8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jones et al. (*J. Labelled Compounds and Radiopharm.* **1996**, 28, 561-565) in view of Dean et al. (WO97/22367) as stated in the office action mailed 12/14/06. The modified rejection is necessitated by the cancellation of claims 11 and 12.

Art Unit: 1618

5. Applicant asserts that Jones et al. fails to teach the specific location of the tritium labeling on the growth hormone secretagogue MK0677.

6. It would be obvious that the growth hormone secretagogue MK0677 molecule of Jones et al. may contain a tritium label at any point that contains a hydrogen, including the methyl substituents that are equivalent to the R^{1-6} of the instant claims. Therefore the tritium labeled growth hormone secretagogue MK0677 compound of Jones et al. encompasses the compound of the instant claims.

7. Applicant asserts that Dean et al. teaches away from tritium labeling growth hormone secretagogues.

8. Dean et al. teaches away from tritium labeling the peptide ligands derived from GHRP-6 which is a completely different compound than that of MK0677. Therefore this information bears no credence to the tritiation of MK0677 and its use for the methods of Dean et al. Jones et al. teaches that the tritium labeled MK0677 is stable, decomposes less rapidly and have high specific activities as does the S-35 labeled MK0677. The reference of Dean et al. was used to provide for the teaching of the method for identifying a compound that can bind to a growth hormone secretagogue receptor and teaches of the assay to test compounds for their growth hormone secretagogue activity. The assay comprises contacting a compound suspected of being a growth hormone secretagogue with a growth hormone secretagogue receptor, such as a biological sample/host in the presence a growth hormone secretagogue and monitoring whether the compound suspected of being a growth hormone secretagogue influences the binding of the compound to the growth hormone secretagogue receptor.

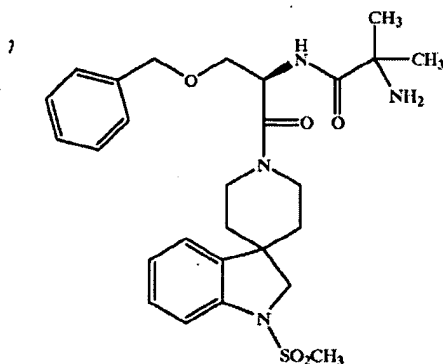
Art Unit: 1618

Although Dean et al. describes a S-35 labeled MK0677 molecule, it would be obvious from the combination of the disclosures to utilize a radiolabeled MK0667, such as tritiated for the methods of Dean et al. since both the S-35 and tritiated are equally as favorable.

9. Claims 1-3 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hakkinen (US 6,548,501B2) as stated in the office action mailed 12/14/06. The modified rejection is necessitated by the cancellation of claims 11 and 12.

10. Applicant asserts that Hakkinen merely discloses generic growth hormone secretagogue compound of formula I which may have one or more of its atoms replaced with tritium. Applicant also asserts that Hakkinen does not teach the tritium isotope of MK0677 or the precise location of such isotopes.

11. Hakkinen discloses the compound (below) which is MK0677 and that the MK0677 may contain a tritium isotope at any of its atom positions which includes the methyl groups that are equivalent to the R¹⁻⁶ of the instant claims. Therefore the tritium labeled MK0677 of Hakkinen encompasses the compound of the instant claims.



Art Unit: 1618

12. Applicant asserts that Hakkinen does not teach which certain isotopically labeled compounds would be useful in binding assays, etc.

13. It would be obvious to one skilled in the art that any of the isotopically labeled compounds of the disclosure of Hakkinen would be useful in the binding assays, etc. described, this includes the tritium labeled MK0677.

14. Applicant asserts that in light of Dean et al.'s teaching that previous attempts to develop tritium-labeled peptide ligands from GHRP-6 met with at best limited success.

15. Although the rejection over Hakkinen does not utilize Dean et al., Dean et al. teaches away from tritium labeling the peptide ligands derived from GHRP-6 which is a completely different compound than that of MK0677. However, this information bears no credence to the tritiation of MK0677 and its use for the methods of Dean et al.

Conclusion

No claims are allowed at this time.

16. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

Art Unit: 1618


the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa Perreira whose telephone number is 571-272-1354. The examiner can normally be reached on 9am-5pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MP
April 12, 2007



MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER